



Pharmaceuticals Inc.

FDA Facsimile Approved 07/28/1999

Percocet1999-00174

Page 1 of 2

A. Patient information

1. Patient Identifier [redacted]	2. Age at time of event: 71.000 or Date of Birth: 08/18/1928	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)	<input type="checkbox"/> disability
<input type="checkbox"/> death	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> life threatening	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> other: _____

3. Date of event (month/day)	12/15/1999	4. Date of this report (month/day)	02/01/2000
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5. Describe event or problem

Initial notification(12/28/99):

A 71-year old female patient was hospitalized for an AST LEVEL OF 2,000 IU/L while participating in an open labelled post marketing study for Isoptin SR. She was also taking Percocet (dosage and therapy dates unknown) concomitantly for pain control. She had a history of hypertension and coronary artery disease and was started on Isoptin SR 120 mg QD for hypertension on 12/02/99. On 12/15/99, the patient's blood was analyzed and found to have an AST level of 2,000 IU/L, prompting her hospitalization. Her prothrombin time and hematocrit value were 8 secs and 20% respectively. She developed ATRIAL FIBRILLATION on the night of admission and was transferred to ICU. Treatment (not cont. on following page)

6. Relevant tests/laboratory data, including dates

Test	Value	Units	Date
AST	2,000	IU/L	12/15/1999

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol abuse, hepatic/renal dysfunction, etc.)

Had history of hypertension, coronary artery disease, hypercholesterolemia.

*Had history of osteoporosis causing low back pain.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 Percocet	Endo
#2 Isoptin SR	120 MG Knoll
2. Dose, frequency & route used	
#1 6 TABS DLY PO	#1 1998 - 12/1999
#2 QD PO	#2 12/02/1999 - Unknown
3. Therapy dates (if unknown, give duration)	
4. Diagnosis for use (indication)	
#1 *low back pain due to osteoporosis	5. Event abated after use stopped or dose reduced
#2 Hypertension	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#1 UNK	7. Event reappeared after reintroduction
#2 UNK	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
8. NDC # - for product problems only (if known)	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
Potassium	Unknown
Acetylsalicylic acid	Unknown
Ornade	Unknown

G. All manufacturers

1. Contact office -name/address (& mfring site for devices)	2. Phone Number
Endo Pharmaceuticals Inc. 223 Wilmington West Chester Pike Chadds Ford, PA 19317	(610) 558-9800
3. Report source (check all that apply)	
<input type="checkbox"/> foreign	
<input type="checkbox"/> study	
<input type="checkbox"/> literature	
<input type="checkbox"/> consumer	
<input checked="" type="checkbox"/> health professional	
<input type="checkbox"/> user facility	
<input type="checkbox"/> company representative	
<input type="checkbox"/> distributor	
<input type="checkbox"/> other:	
4. Date received by manufacturer (month/day)	5. (A) NDA # 85-106
12/28/1999	IND # _____
6. If IND, protocol #	PLA # _____
7. Type of report (check all that apply)	pre-1938 <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up # 1	8. Adverse event term(s)
9. Mfr. report number	SGOT INCREASED
Percocet1999-00174	FIBRILLATION ATRIAL

E. Initial reporter

1. Name & address	phone #
Rossano Cornejo, MD Knoll Pharmaceutical Company Mount Olive, New Jersey 07828	(973) 426-2600 x6006
2. Health professional?	3. Occupation
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Specialist, CDS
4. Initial reporter also sent report to FDA	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk	

FDA
3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

DSS

FEB 14 2000

FEB 11 2000

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FDA Form 1000-1000000000

Form report #	Percocet1999-00174
UP-Data report #	
FDA Use Only	

Section B5, Description of event/problem continuation (as necessary):

specified) was initiated. The outcome of the events is unknown. The investigator considered the events as unlikely related to the study medication.

*Follow-up information (01/27/00):

On the night she was admitted to the ICU for atrial fibrillation, patient was given a total of 25 mg of Atenolol IV drip. Isoptin SR was discontinued. She was taking Percocet 6 tablets/day concomitantly for low back pain for approximately one year. The investigator reported that the liver enzyme elevation was due to liver toxicity caused by the acetaminophen content of Percocet and Tylenol which patient was taking for low back pain. The patient recovered with sequela on 12/27/99 and was discharged from the hospital.

This report was received from Knoll Pharmaceutical Company.

Section B6, Relevant tests/laboratory data continuation (as necessary):

Test	Value	Units	Date
Hematocrit	20 %		
Prothrombin time	8	sec.	

Section B7, Other relevant history continuation (as necessary):

Sections C1-8, Suspect medication(s) continuation (as necessary):

Name	Dose, frequency & route used	Therapy dates	Diagnosis for use	Lot # Exp. date	Event abated/ Event reappears
*Tylenol	TAB PO	Unknown - 12/1999	low back pain	UNK	NA NA

Section C10, Concomitant medical products continuation (as necessary):

Name	Therapy dates
Aerobid	Unknown
Valium	Unknown
Albuterol	Unknown

Section G8, Adverse event term(s) continuation (as necessary):

ANAEMIA

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FEB 14 2000

FEB 11 2000